



Potential Designated Chemical Triclocarban (TCC)

Carl D'Ruiz¹, MPH; Felix Ayala-Fierro¹, PhD, DABT;
Luanne Jeram², MS

¹Henkel Consumer Goods, Inc.

²LANXESS Corporation

Presentation to Scientific Guidance Panel

May 24, 2010

Regulatory status

- TCC has been used safely in consumer products world-wide for over 40 years
- In the U.S., TCC is regulated as antibacterial agent under the Food and Drug Administration (FDA) Tentative Final Monograph (TFM) for Topical Antiseptic Drug Products.
- Extensive information exists on human health and environmental safety of Triclocarban.
 - This data is publicly available and has been submitted to numerous government agencies

Regulatory status

- TCC has been reviewed for safety globally
 - The European Union Scientific Committee on Consumer Products (SCCP) concluded in 2005 that the use of TCC for non-preservative purposes in cosmetic rinse-off hand and body care products up to a maximum concentration of 1.5% does not pose a direct risk to the health of the consumer.
 - TCC is approved as a preservative for cosmetics with a maximum permissible concentration of 0.2% under the European Union Cosmetic Products Directive
 - TCC is approved for use as an antimicrobial in cosmetic products in Switzerland at a maximum use concentration of 0.2%
 - TCC is also listed in the Japanese Cosmetic Standard as a preservative for cosmetic products with a maximum use concentration of 0.3% for leave-on cosmetics and no specified upper limit for rinse-off cosmetics.

Use and Exposure

- Limited use as antibacterial agent
 - Used exclusively in bar soaps as antimicrobial
 - Small uses in deodorants
 - Not used in *liquid soap* or body wash in the US
- Product/import volume
 - 2005-2010: < 500,000 pounds
- Primary human exposure via personal care products
 - Acceptable Margin of Exposure

Environmental Occurrence

- Found in surface waters
 - Efficiently removed by WWTP's (88-97%)
 - Low levels in surface (effluent) waters (<1ppb)
- Removed in sewage sludge
 - 76% sorbed into sludge
 - TCC is biosolids-bound (not available)
 - Biosolids land application results in low ppm levels (0.21 mg/kg soil)



Known or suspected health effects

- Reproductive effects at high doses in animals
 - No effects at 1000 mg/kg/d. NOEL=25 mg/kg/d
- Endocrine disruption
 - Cell culture experiments are not considered representative of human exposure levels
- Possible presence of chloroanilines
 - Low levels of chloroanilines in USP grade TCC



Persistence and bioaccumulation

- Persistence:

- Half-life depends on the type of soil

- Bioaccumulation

- Aquatic organisms

- Low bioconcentration factor reported

- Terrestrial organisms

- Recent data shows low bioconcentration factor



Pharmacokinetics and metabolism

- Finding of early studies

- ☐ Low dermal absorption from rinse-off products
- ☐ TCC metabolized to glucuronide metabolites

- Excretion

- ☐ TCC metabolites excreted primarily in urine



Biomonitoring

- TCC is eliminated through the urine
 - Not retained in the body
- TCC levels in blood anticipated at low ppb levels
 - TCC not detected in breast milk
 - Industry not aware of current on-going research studies (UC Davis)



Conclusions

- TCC has been used safely for more than 40 years across the globe
- There is extensive data available on the human and environmental safety of TCC
- The safety of TCC has been reviewed by several authoritative bodies which have concluded that the ingredient is safe for its intended uses

Conclusions, cont.

- Triclocarban is not widely used as commonly thought
- Triclocarban is eliminated from the body
- Endocrine disruption from *in vitro* systems are very difficult to extrapolate to humans
- Triclocarban should be a low priority for biomonitoring
 - Low annual volumes
 - Low consumer exposure
 - Acceptable margins of exposure